

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND  
COMPOUNDING PHARMACY, INC.  
PRODUCTS LIABILITY LITIGATION

MDL No. 1:13-md-2419-FDS

This Document Relates To:

All Actions

**MDL Order No. 6**

June 28, 2013

**CASE MANAGEMENT ORDER**

This order establishes further case management procedures in *In re New England Compounding Pharmacy, Inc., Products Liability Litigation*, MDL No. 1:13-md-2419-FDS (“the MDL”).

**I. SCOPE OF ORDER**

This order applies to all actions transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to its order of February 12, 2013; any tag-along actions transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to Rule 7.4 of the Rules of Procedure of that Panel; any related actions originally filed in this Court or transferred or removed to this Court; and any related actions subsequently filed in this Court or otherwise transferred or removed to this Court.

For the purposes of this order, “NECC” shall mean New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center; “affiliated defendants” shall mean

**EXHIBIT A**

other entities or individuals affiliated with NECC; and “unaffiliated defendants” shall mean other entities not affiliated with NECC.

## **II. CASE ADMINISTRATION**

### **A. Status Conferences**

The Court expects to conduct a status conference about once a month, on such dates and at such times as it deems appropriate. Plaintiffs’ Steering Committee, the defendants, the trustee appointed in the chapter 11 case of NECC, the official committee of unsecured creditors in the chapter 11 case (the “Creditors’ Committee”), and any other interested parties may participate in the status conferences.

Attorneys may listen to the monthly status conferences by telephone. Plaintiffs’ lead counsel shall provide the Court with a list of plaintiffs’ attorneys; Creditors’ Committee members, member representatives, and attorneys; and the trustee’s representatives and attorneys who will participate by phone and shall distribute the dial-in number to those counsel. Counsel for Ameridose, LLC shall provide the Court with a list of defendants’ attorneys who will participate by phone and shall distribute the dial-in number to those counsel. Any attorney who wishes to be heard by phone must obtain permission from the Court to do so before the status conference by contacting the Court’s clerk.

The Plaintiffs’ Steering Committee, the defendants, the trustee, and the Creditors’ Committee should confer on a proposed agenda in advance of each conference. The parties shall endeavor to submit a joint agenda to the Court the day before each conference. To the extent that the parties cannot agree, separate agenda items may be submitted the day before the status conference.

**B. Master Service List and Waiver of Service of Formal Process**

Plaintiffs' lead counsel shall create and maintain an up-to-date service list of plaintiffs' counsel in the MDL. Such list shall be provided monthly to the Court, the trustee, and defense liaison counsel the day before each scheduled status conference. All filings by any party shall be accomplished via ECF.

The following defendants have agreed to waive formal service of process of all complaints filed in and/or transferred to the MDL in accordance with the procedure set forth herein:

1. Ameridose, LLC;
2. Barry J. Cadden;
3. Lisa Conigliaro Cadden;
4. Glenn A. Chin;
5. Gregory Conigliaro;
6. GDC Properties Management, LLC;
7. Medical Sales Management, Inc.;
9. Doug Conigliaro;
10. Carla Conigliaro; and
11. Alaunus Pharmaceuticals, LLC.

Plaintiff's counsel wishing to obtain waiver of formal service of process from the above mentioned defendants must provide the following to each defendant's counsel, via first-class certified mail:

1. affidavit of waiver of service of formal process;
2. a true copy of the complaint;

3. a true copy of the civil action cover sheet;
4. a true copy of the summons; and
5. a postage pre-paid return envelope.

Upon receipt of those materials by first-class mail, counsel for defendant shall execute the affidavit of waiver of service of formal process and return it to plaintiff's counsel within 14 days. Plaintiff's counsel shall then file an affidavit of waiver of service of formal process with the court within the timeframe required by Rule 4.

The parties have agreed that by complying with the procedure set forth herein, a plaintiff has fulfilled his or her obligations under Rule 4.

**C. Existing Orders**

The orders previously entered in *Erkan v. New England Compounding Pharmacy, Inc. et al.*, 12-cv-12052, apply to all actions in the MDL unless superseded or modified by a later order of this Court. These include, but are not limited to, the preliminary injunction order (Dkt. No. 38), the inspection orders (Dkt. Nos. 100, 126), and the preservation orders (Dkt. Nos. 110, 111, 112).

Plaintiffs' Steering Committee, NECC, the affiliated defendants, and the Creditors' Committee may, after meeting and conferring, jointly or otherwise ask the Court to modify provisions of the preservation orders if complying with those orders becomes unduly burdensome or unnecessary.

Nothing in this order shall prevent any party from moving for a stay of discovery or other proceedings for any reason, or from opposing such a motion.

**D. Answer Dates**

All deadlines for responding to complaints, filing dispositive motions, or responding to dispositive motions to dismiss are temporarily stayed. No defendant need answer any complaint until further order of this Court. These deadlines will be revisited as discovery progresses. Notwithstanding that stay, Alaunus Pharmaceutical, LLC has voluntarily agreed to extend the stay to the deadlines for responding to its motions to dismiss under Rule 12(b)(6) and may terminate the stay as to those deadlines by filing a notice in the MDL docket. Any plaintiff who has not filed an opposition to those Rule 12(b)(6) motions shall then have 30 days from the date of the filing of the notice to do so.

**E. Waiver of Pre-suit Notice Requirements**

Each of the following defendants have agreed to waive the applicability of any “state law suit requirements,” including, but not limited to, any state law or state court rule requiring: notices of intent to sue; affidavits of merit; certifications of expert review; review by any attorney, expert, tribunal and/or panel; pre-suit arbitration; or similar pre- or immediate-post-suit action concerning the substantive merits of a claim. Plaintiffs have agreed to waive applicability of any state law or state court rule requiring any of the following defendants to engage in or file, as a condition of answering a complaint: responses to a notice of intent to sue; affidavits of merit; certifications of expert review; review by any attorney, expert, tribunal or panel; or similar pre- or immediate-post-suit action concerning the substantive merits of a claim or defense. Any pleading or motion asserting the applicability of any “state law suit requirements” described herein, whether considered procedural or jurisdictional, is deemed struck as to these parties. Individual parties may move the Court for additional, appropriate relief.

The Defendants who have waived the “state law suit requirements” are:

1. NECC;
2. Ameridose, LLC;
3. Barry J. Cadden;
4. Lisa Conigliaro Cadden;
5. Glenn A. Chin;
6. Gregory Conigliaro;
7. GDC Properties Management, LLC;
8. Medical Sales Management, Inc.;
9. Doug Conigliaro;
10. Carla Conigliaro; and
11. Alaunus Pharmaceuticals, LLC

Other defendants may opt to similarly waive these requirements by notifying the Plaintiffs’ Steering Committee.

**F. Tolling**

The Plaintiffs’ Steering Committee and affiliated defendants should meet and confer about an agreement to toll the limitations period, for a reasonable period of time, on claims against the affiliated defendants filed in the MDL, or that will be filed in the MDL, to which a one-year statute of limitations applies. If they reach agreement, they should jointly submit a proposed tolling agreement by July 7, 2013. The parties may, if they agree, implement a bar date process into the same tolling agreement.

No action taken pursuant to this order shall in any manner interfere with the trustee’s or the

affiliated defendants' rights or obligations under the Agreed-Upon Order Establishing Protocol for Settlement Negotiations and Communications entered in the chapter 11 case (*Moore v. Cadden*, Adv. Pro. No. 13-01040-HJB at Dkt. No. 96 (Bankr. D. Mass. Apr. 18, 2013)), including, but not limited to, the right to enter into a separate tolling agreement.

**G. Stipulation Regarding Direct Filing of New Federal Cases into the MDL**

In order to eliminate delays associated with transfer of cases filed in or removed to other federal district courts to this Court as part of the MDL and to promote judicial efficiency, defendants have stipulated and agreed that they will not assert any objection of improper venue as to any NECC-related case alleging personal injury and/or wrongful death filed directly in the District of Massachusetts that is properly included in the MDL, where venue may otherwise appropriately lie in a federal district outside the District of Massachusetts, except as provided below.

The defendants' stipulation and agreement are contingent on the understanding that they have not waived their rights to transfer any case in the MDL to a court of proper venue under 28 U.S.C. § 1406(a) or, if applicable, under 28 U.S.C. § 1334(c)(1). Furthermore, upon the completion of all pretrial proceedings applicable to a case directly filed in the District of Massachusetts pursuant to this stipulation regarding filing in the MDL, the Court (1) pursuant to 28 U.S.C. § 1404(a), may transfer the case filed directly in the District of Massachusetts to a federal district court of proper venue as defined in 28 U.S.C. § 1391, based on the recommendations of the parties to that case, or, if the parties cannot agree, based on its own determination after briefing from the parties; or (2) pursuant to 28 U.S.C. § 1334(c)(1), may remand the case filed directly in the District of Massachusetts to a state court of proper venue, based on the recommendations of the parties to that case, or, if the parties cannot agree, based on its own determination after briefing from the parties.

Any action seeking to take advantage of the venue provisions of this section must be pursuant to a complaint filed: (1) by an individual plaintiff on behalf of him or herself or on behalf of an injured minor child for which the individual is guardian or next friend; (2) by a plaintiff and family member plaintiffs; or (3) on behalf of an appointed representative of the estate of a deceased or incompetent individual, together with any family members and/or beneficiaries of such estate. Other than as expressly provided above, a complaint may not be filed without the prior approval of this Court. Multi-plaintiff complaints or complaints joining two or more plaintiffs not related by blood or marriage may not be filed without the prior approval of this Court.

#### **H. Settlement Discussions with the Affiliated Defendants**

The trustee is currently engaged in settlement discussions with NECC and the affiliated defendants, pursuant to the Agreed-Upon Order Establishing Protocol for Settlement Negotiations and Communications entered in the chapter 11 case. Plaintiffs' lead counsel and the Creditors' Committee should be kept apprised of the status of that process to the extent permitted by the Bankruptcy Court.

The Plaintiffs' Steering Committee may nonetheless commence formal discovery against any one or more affiliated defendants upon a showing of good cause to this Court.

#### **I. Settlement Discussions with Unaffiliated Defendants**

To the extent that there are settlement discussions with unaffiliated defendants, or entities who are otherwise non-parties to the MDL, outside of the context of the ongoing settlement discussions with affiliated defendants discussed in the previous section, the Plaintiffs' Steering Committee, the Creditors' Committee, and the trustee may participate in those settlement discussions.



The Plaintiffs' Steering Committee, the Creditors' Committee, and the trustee shall each have an opportunity to provide input into any discussions of settlement, mediation, resolution through bankruptcy channels, or any other form of resolution, and shall seek to approach and engage in these discussions in a coordinated, cooperative manner.

To the extent that any communications about resolution of claims against the unaffiliated defendants or non-parties take place without a designee from each of the Plaintiffs' Steering Committee, the Creditors' Committee, and the trustee, the designee who received or was involved in said communication shall promptly notify the absent designee(s) about those communications and shall thereafter ensure that further discussions occur with a full complement of designees present in accordance with this section.

Plaintiffs' lead counsel and the Creditors' Committee may each designate one or more members or member representatives to participate in settlement discussions with unaffiliated defendants and non-parties. Plaintiffs' lead counsel and the Plaintiffs' Steering Committee have designated national defendant and state-specific defendant chairs as Plaintiffs' lead counsel's designees for settlement discussions on behalf of lead counsel and the Plaintiffs' Steering Committee. The Plaintiffs' Steering Committee designee is required to consult with the Plaintiffs' Steering Committee and lead counsel, and cannot bind them to any decision. The Creditors' Committee may designate one or more members or member representatives to participate in settlement discussions with unaffiliated defendants and non-parties. The Plaintiffs' Steering Committee's designee(s) and the Creditors' Committee designee(s) should communicate and cooperate with respect to settlement discussions.

**J. Mediation with Unaffiliated Defendants and Non-Parties**

The Plaintiffs' Steering Committee, the trustee, and the Creditors' Committee shall confer and shall submit to the Court within 30 days a proposed mediation order to be entered in this Court and the Bankruptcy Court concerning all unaffiliated defendants and non-parties.

In order to participate in the mediation program, an entity or individual will be required to produce, informally, materials and information necessary for effectively mediating claims. The Plaintiffs' Steering Committee, the Creditors' Committee, and the unaffiliated entities or individuals who wish to participate in the mediation process should discuss and agree upon what materials an entity or individual must produce in order to participate in mediation.

Participation in this mediation process is at will. Plaintiffs' lead counsel, the Creditors' Committee, the trustee, or the unaffiliated defendants and non-parties may withdraw from that process as to any particular unaffiliated defendant or non-party at any time and proceed with litigation as to such unaffiliated defendant or non-party in a manner consistent with this order.

The proposed mediation order shall provide that any unaffiliated defendant or non-party who elects to participate in mediation shall, among other things:

1. be exempt from discovery except as required to facilitate participation in mediation.

The exemption should continue in force so as long as the mediator does not report to this Court and the Bankruptcy Court that (a) the subject defendant or potentially responsible party is not negotiating in good faith; (b) that the mediation as to the defendant or potentially responsible party has reached impasse terminating mediation as to them; or © that the mediation as a whole has reached impasse and should be terminated. The election shall require the defendant or potentially responsible

entity/person to submit to jurisdiction of this Court and Bankruptcy Court;

2. voluntarily agree to a standing injunction order tolling any statutes of limitation or other applicable time bar statutes;
3. voluntarily agree to a standing injunction order suspending or extending any and all applicable pre-suit or post-suit requirements related to health care orders, including any notices, arbitration or panel submission requirements, or affidavits of service;
4. provide a statement to the appointed mediator, the Plaintiffs' Lead Counsel, a liaison to the defendants, the trustee, and the Creditors' Committee identifying any other potentially responsible parties liable to tort claimants or liable to the defendants or another potentially responsible party regarding injuries related to the allegedly contaminated methylprednisolone acetate and the grounds or basis of the claim. Statements should be deemed mediation material and not admissions, and are not admissible in any judicial proceeding; and
5. file a proof of claim in the chapter 11 case.

### **III. COORDINATION WITH OTHER ACTIONS**

To the extent that there are NECC-related cases pending in state courts that are not a part of the MDL, but that fall within the subject matter definition of the MDL, this Court intends to coordinate with the state courts presiding over such cases, to the extent that such state courts are amenable. The Court may issue more detailed orders regarding such coordination, should the need arise.

The federal-state liaison counsel shall update the Court on the status of state court actions at each status conference.

The Plaintiffs' Steering Committee and the Creditors' Committee shall appoint a designee to meet telephonically or in person on a regular basis, but no less than once a week, to discuss status and strategy of the MDL cases and the chapter 11 case, including with respect to settlement negotiations. Within 30 days, the Plaintiffs' Steering Committee and the Creditors' Committee shall enter into a common interest agreement in form and substance reasonably acceptable to both parties. The trustee may elect to participate in the meetings between the Plaintiffs' Steering Committee and the Creditors' Committee; otherwise the Plaintiffs' Steering Committee and the Creditors' Committee should keep the trustee apprised of the status of the process.

#### **IV. PRETRIAL PROCEDURES AND SCHEDULE**

##### **A. Plaintiff Profile Sheets**

The Plaintiffs' Steering Committee, the defendants, the trustee, and the Creditors' Committee should meet and confer about an appropriate plaintiff profile sheet, to be addressed by subsequent order.

##### **B. Medical Authorization Releases**

The Plaintiffs' Steering Committee, the defendants, the trustee, and the Creditors' Committee should meet and confer about an appropriate medical authorization release and medical records retrieval, to be addressed by subsequent order.

##### **C. Master and Short Form Complaints**

The Plaintiffs' Steering Committee shall file a master complaint by September 5, 2013, after meeting and conferring with the defendants and the trustee. This deadline is intended to permit the

Plaintiffs' Steering Committee a period of time to conduct discovery and incorporate the fruits of that discovery into the master complaint. The Plaintiffs' Steering Committee shall also provide a short form complaint by September 5, 2013, after meeting and conferring with the defendants and the trustee. The filing of a master complaint or short form complaint will not render the motions to dismiss of Alaunus Pharmaceutical, LLC or any other defendant moot. Defendants may move to dismiss under Rule 12(b)(6) against plaintiffs' original complaints.

By October 1, 2013, MDL plaintiffs who have already filed a complaint as of the filing of the master complaint may file short form complaints or, with leave of the Court, amended complaints.

**D. Discovery**

**1. Discovery Schedule**

Formal discovery of NECC and the affiliated defendants shall remain temporarily stayed as set forth in this order and the previous orders of the Court.

Subject to a stay of discovery for mediation participants in accordance with a mediation order, formal discovery of unaffiliated defendants and non-parties shall be conducted by the Plaintiffs' Steering Committee as follows:

1. written discovery (including, but not limited to, requests for production, interrogatories, requests for admissions, and subpoenas duces tecum) may commence immediately and must be served in time to be returnable as soon as practicable; and
2. depositions of witnesses and/or corporate designees, including but not limited to, the following entities may be taken and completed as soon as practicable: ARL

Bio Pharma, Inc., Liberty Industries, Inc., UniFirst Corporation and its subsidiary UniClean, St. Thomas Outpatient Neurosurgical, Specialty Surgery Center, Curtis Pharmaceuticals, and CuraScript, Inc., and Michigan Pain Specialists, PLLC. The Plaintiffs' Steering Committee should consult with defense liaison counsel in scheduling depositions.

## **2. Mandatory Production to Plaintiffs' Steering Committee**

Any formal discovery produced by any plaintiff, defendant or non-parties in any of the MDL cases or any other civil actions involving allegations of injury from use of an NECC product, must also be produced to the Plaintiffs' Steering Committee no later than seven days after production elsewhere. Documents must be sent to lead counsel's attention in the format produced elsewhere (whether electronic or hard copy):

HAGENS BERMAN SOBOL SHAPIRO LLP  
Attn: Mike Barker  
55 Cambridge Parkway, Suite 301  
Cambridge, MA 02142

Lead counsel should make these documents available through a document repository, as described below.

An electronically stored information protocol outlining the format of production of documents will be addressed in a subsequent order. The default should be that all documents are produced in their native format (for example, in Word, Excel, or PowerPoint format for electronic documents or photocopies for hardcopy documents) in order to minimize burden and expense incurred.

## **3. Privilege Logs**

The form and content of privilege logs for documents withheld (or redacted) on privilege or work product grounds will be addressed in a subsequent order.

**4. Authentication of Documents**

The process for authenticated documents produced in discovery will be addressed in a subsequent order.

**5. Document Repository**

The Plaintiffs' Steering Committee shall create and maintain an online document repository accessible (at minimum) by the Creditors' Committee, the trustee, and plaintiffs' counsel of record in any action alleging injury related to a plaintiff's use of a product sold by NECC with the understanding that access to proprietary fields of information can be restricted. The Plaintiffs' Steering Committee and the Creditors' Committee should meet and confer with the trustee and the defendants with the goal of creating a single document repository that is accessible to all of those entities in order to minimize costs.

The Plaintiffs' Steering Committee shall make all formal discovery produced by plaintiffs, defendants or non-parties pursuant to Section IV.D.2. available through this or another online document repository, subject to certain conditions. Any plaintiffs' or defendants' counsel who seeks access to the repository must comply with any confidentiality order and/or protective order entered in this case. In addition, any counsel may be (at the Plaintiffs' Steering Committee's discretion) subject to a reasonable assessment or cost-sharing arrangement as a condition precedent to use of the repository. The Plaintiffs' Steering Committee shall agree with the Creditors' Committee as to any assessment, if any, required to access the repository.

All materials produced by defendants or non-parties to the Creditors' Committee

pursuant to formal discovery shall be timely provided to the Plaintiffs' Steering Committee and made available through the repository.

Materials produced informally or pursuant to a confidentiality or protective order by the trustee to the Plaintiffs' Steering Committee or the Creditors' Committee shall not be made available through the repository.

**E. Confidentiality of Communications with Experts**

The confidentiality of communication with experts will be addressed in a subsequent order.

**F. Chapter 11 Plan**

The Plaintiffs' Steering Committee, the trustee, and the Creditors' Committee should confer regarding formulation of a chapter 11 plan in the Bankruptcy Court. This order does not withdraw the reference to the Bankruptcy Court in connection with the chapter 11 case, including but not limited to negotiation and formulation of a bankruptcy plan, plan issues, plan disclosure requirements, plan confirmation, and Plan implementation or enforcement. The parties may seek, or oppose, in whole or in part, withdrawal of the reference to the Bankruptcy Court.

**G. Reservation of Rights**

The Plaintiffs' Steering Committee's duties run to all plaintiffs with cases in the MDL currently or later filed in or transferred to the MDL. Except as otherwise provided herein, nothing in this order shall diminish the obligations of lead counsel and the Plaintiffs' Steering Committee to discharge their duties under MDL Order No. 2.

The Creditors' Committee duties run to all creditors with unsecured claims against



NECC. Except as otherwise provided herein, nothing in this order shall limit, restrict or otherwise affect the authority and duties of the Creditors' Committee, as provided by 11 U.S.C. §§ 1102 and 1103, including, but not limited to, the following statutory duties: (1) to consult and participate with the trustee concerning the administration of the chapter 11 case; (2) to investigate the acts, conduct, assets, liabilities, and financial condition of NECC, the operation of NECC's business and the desirability of the continuance of such business, and any other matter relevant to NECC's chapter 11 case or to the formulation of a bankruptcy plan, including, without limitation, investigating claims by NECC against other parties or by other parties against NECC; (3) to participate in the formulation of a bankruptcy plan, advise creditors on the Creditors' Committee's determinations as to any bankruptcy plan formulated, and collect and file with the Court acceptances or rejections of a bankruptcy plan, including, without limitation, negotiating with the trustee, unsecured creditors (including any holders of personal injury, tort, and wrongful death cases against NECC and any holders of asserted or contingent indemnity, contribution, or similar claims against NECC) and other relevant parties contemplated to be included in, part of or impacted a bankruptcy plan any and all plan or plan-related content, provisions and related agreements; and (4) to communicate with and provide access to information to any and all unsecured creditors of NECC (including any holders of personal injury, tort, and wrongful death cases against NECC and holders of asserted or contingent indemnity, contribution, or similar claims against NECC).

**V. TIMELINE OF EVENTS**

<b>Event</b>	<b>Date / deadline</b>
Fact discovery as to NECC and the affiliated defendants	Temporarily stayed.
Fact discovery as to unaffiliated defendants and non-parties	Open, subject to any proposed mediation order that is entered by the Court.
Motion(s) for entry of a confidentiality order filed	July 3, 2013
Plaintiffs' Steering Committee, defendants, Trustee, and Creditors' Committee to meet and confer about scope of initial discovery of plaintiffs	July 9, 2013
Plaintiffs' Steering Committee, Trustee, and Creditors' Committee to propose mediation order for unaffiliated defendants	July 3, 2013
Fact discovery as to unaffiliated defendants and non-parties returnable by	July 30, 2013
Discovery depositions as noted above	August 1, 2013
Depositions as to unaffiliated defendants and non-parties complete	August 15, 2013
Master complaint filed	September 1, 2013
Deadline to file amended complaints for cases filed before September 1, 2013	Fall 2013
Case-specific discovery of plaintiffs	Fall 2013
Summary judgment briefing	Fall 2013
Expert reports exchanged and depositions conducted	Fall 2013
Trial(s)	Summer 2014

Nothing in this order shall prevent any party from moving for a stay of discovery or other proceedings for any reason, or from opposing such a motion.

**So Ordered.**

/s/ F. Dennis Saylor  
F. Dennis Saylor IV  
United States District Judge

Dated: June 28, 2013